K003956 (1 OF 3)

**Bard Interventional Products Division**
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

JAN - 5 2001

BARD

## VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

| | |
|---|---|
| Submitter's Name: | Bard Interventional Products<br>C.R. Bard, Inc. |
| Address: | 129 Concord Road, Bldg. #3<br>Billerica, MA 01821 |
| Phone: | (978) 262-4866 |
| Fax: | (978) 262-4878 |
| Contact Person: | Beth A. Zis, R.A.C. |
| Date of Preparation: | November 17, 2000 |

B. Device Name

| | |
|---|---|
| Trade Name: | Bard® EndoCinch™ Suturing System |
| Common/Usual Name: | Suturing Device |
| Classification Name: | Endoscopes and accessories |

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C. Predicate Device Name(s)
Trade Name:

Bard® Endoscopic Suturing System
Bard Interventional Products, Division of C. R. Bard, Inc.

Y-Knot Suture Clip
Innovasive Devices, Inc.

SutureLok
Smith & Nephew, Inc., Endoscopy Division

D. Device Description:
The Bard® EndoCinch™ Suturing System is a multi-component system consisting of a reusable handle, disposable capsule assembly, needle assembly, guidewire, pusher wire, clip delivery device, suture clip loader, suture clips, suture loader, suture loop tools and suture tag assemblies. Only the Bard® Endoscopic Handle and Bard® Suture Tags may be used with the Bard® EndoCinch™ Suturing System.

E. Intended Use:
For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic Gastroesophageal Reflux Disease.

F. Technological Characteristics Summary:
The Bard EndoCinch Suturing System is substantially equivalent to the Bard Endoscopic Suturing System. The system will now contain a clip delivery device and suture clips to secure the suture. The ring and plug of the suture clip are mated together to secure the two ends of the suture through manual actuation of the handle. This fixation, like the predicate devices, replaces

the knot component of the suture tag assembly. The clip delivery device also will cut the suture once the suture clip is secured by manually actuating the handle. The suture clips and delivery device will replace the current suture cutter and knot pushing devices contained in the kit. The remaining components of the current suture kit and the reusable handle are not changing.

G. Performance Data

Comparative performance testing was done, where appropriate, between the proposed EndoCinch™ suture clips and the current polypropylene knot. The clip delivery device was tested to assure that the suture clips can be delivered to cinch and cut the suture and the critical joints of the clip delivery device underwent tensile testing.

Comparative testing of the suture clips to the current knot demonstrated that the suture remains secure when exposed to the simulated conditions of food swallowing, lower esophageal sphincter forces and the gastric environment without degradation or loss of integrity.

Testing also demonstrated that the suture clip can be delivered to the intended location, and can secure and cut the suture in three versus nine intubations of the endoscope as compared to the current knot tying method used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

C. R. Bard, Inc.
c/o Mr. Peter N. Ruys
N. V. Kema
Utrechtseweg 310
NL-6812 AR Arnhem
The Netherlands

Re: K003956
Trade Name: Bard® EndoCinch™ Suturing System
Regulatory Class: II
Product Code: KOG
Dated: November 27, 2000
Received: December 21, 2000

Dear Mr. Ruys:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003956

Device Name: Bard® EndoCinch™ Suturing System

Indications For Use: For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic Gastroesophageal Reflux Disease.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices

510(k) Number K003956